

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

Purl, M.D., et al.,

Plaintiffs,

v.

**United States Department of
Health and Human Services, et al.,**

Defendants.

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Civil Action No. 2:24-cv-228-Z

**PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
AND BRIEF IN SUPPORT**

Plaintiffs Dr. Carmen Purl and Carmen Purl, M.D., PLLC, d/b/a Dr. Purl's Fast Care Walk In Clinic, hereby file this motion for preliminary injunction. Plaintiffs ask the Court to issue an injunction before December 23, 2024, the first compliance date for a new regulation that violates the Administrative Procedure Act. The rule twists regulations issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") into a political tool in the abortion debate, muzzling Plaintiffs from giving the State of Texas information that protects their patients and the public health from harm and abuse. Defendants oppose the motion.

Plaintiffs' motion is supported by a concurrently filed appendix and the brief set forth below.

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BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

The Department of Health and Human Services has inserted abortion and gender identity into a statute that has nothing to do with those controversies. *See* HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (“2024 Rule”). HHS admits that it issued the 2024 Rule in response to *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215 (2022). And because HHS disagrees with *Dobbs*, the agency politicized a neutral law about patient privacy, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). That is outside HHS’s lawful authority.

The 2024 Rule injures doctors and clinics across the country, including Plaintiffs Dr. Carmen Purl and her clinic in Dumas, Texas, where she has spent many years caring for her patients. The 2024 Rule restricts Dr. Purl’s ability to protect her patients by limiting her ability to disclose information about suspected abuse if it involves anything related to “reproductive health care,” including abortion or gender-transition procedures. The 2024 Rule restricts her cooperation with state investigations and compliance with lawful process, like subpoenas and court orders. The 2024 Rule forces Dr. Purl to engage in legal speculation—at her own risk—about when and how HHS’s political appointees believe abortions are legal under their view of the Constitution—and it penalizes Dr. Purl under HIPAA if she guesses wrong. Finally, the 2024 Rule admits covered entities like Plaintiffs must incur unrecoverable compliance costs by December 23, 2024, when its new requirements start to go into effect. The Court should grant a stay under 5 U.S.C. § 705 or issue a preliminary injunction preventing enforcement of the 2024 Rule while judicial review proceeds.

BACKGROUND

I. Carmen Purl, M.D. and Dr. Purl's Fast Care Walk-In Clinic.

Dr. Carmen Purl is a board-certified family practice physician. Purl Decl. ¶ 2, App. 001. She has been practicing medicine since 1986 and received her board certification in 1988. Purl Decl. ¶ 2, App. 001. She is the sole owner of Carmen Purl, M.D., PLLC, d/b/a Dr. Purl's Fast Care Walk In Clinic ("the Clinic"), through which she employs about 18 people. Purl Decl. ¶¶ 1, 3, App. 001. Dr. Purl and three nurse practitioners employed by the Clinic provide healthcare to patients in Dumas, Texas. Purl Decl. ¶ 3, App. 001.

As professionals licensed by the State of Texas, Dr. Purl and her employees are subject to mandatory abuse reporting requirements under Texas law. Purl Decl. ¶ 4, App. 001. Failure to report child abuse or neglect within 48 hours may subject a Texas-licensed professional to criminal penalties, including incarceration. Purl Decl. ¶ 4, App. 001–002. Dr. Purl and her employees have similar obligations if they suspect abuse of a vulnerable adult, such as a patient with a disability or who is elderly. Purl Decl. ¶ 4, App. 001–002. In addition to legal requirements, they have moral and ethical obligations to protect and advocate for patients, including by reporting suspected abuse or crime. Purl Decl. ¶ 4, App. 002.

In her nearly 40 years as a practicing physician, Dr. Purl has encountered many child patients who were abused or neglected, as well as some women and elderly victims. Purl Decl. ¶ 5, App. 002. Dr. Purl estimates that victims of abuse are more likely to be brought to small walk-in clinics like hers than to larger medical facilities. Purl Decl. ¶ 5, App. 002. She has encountered situations in which the likelihood of imminent abuse was so apparent that she caused the patient to remain at the Clinic while she called the local police to intervene. Purl Decl. ¶ 5, App. 002. In other situations, evidence of abuse was not readily apparent and

discovered only later, such as upon review of X-rays that show old fractures or other indications of physical trauma. Purl Decl. ¶ 5, App. 002. When Dr. Purl or her employees have suspected a patient was being abused or neglected, they have made reports to local law enforcement or Texas Child Protective Services (CPS) in accordance with Texas law. Purl Decl. ¶ 5, App. 002.

A significant proportion of the patients at the Clinic are children, young women, and pregnant women. Purl Decl. ¶ 6, App. 002. During flu season, 10 to 20 children can come to the Clinic each day. Purl Decl. ¶ 11, App. 004. The Clinic provides services to many women seeking pregnancy tests, as a positive pregnancy test is a component of the applications for medical coverage under Texas's Medicaid for Pregnant Women and CHIP Perinatal programs. Purl Decl. ¶ 6, App. 002.

The routine collection of information about a female patient includes information about the patient's last menstrual period, her age of menarche, number of pregnancies, and number of live births. Purl Decl. ¶ 7, App. 003. If the number of live births is less than the number of pregnancies, Dr. Purl inquires to determine whether the patient experienced a spontaneous abortion, more commonly known as a miscarriage, or whether the pregnancy was terminated by an induced abortion. Purl Decl. ¶ 7, App. 003. In her experience, a thorough gynecologic history will include most or all of this patient information. Purl Decl. ¶ 7, App. 003.

Dr. Purl's practice regularly includes caring for pregnant women and girls. Purl Decl. ¶ 8, App. 003. It is common for Dr. Purl and clinic employees to encounter adolescent girls who are under the age of consent and are pregnant or report sexual activity. Purl Decl. ¶ 8, App. 003. Dr. Purl estimates she has treated hundreds of such girls and has delivered babies from mothers as young as 12 years old. Purl Decl. ¶ 8, App. 003. Dr. Purl further estimates that she has treated more than 100 children who were victims of sexual abuse, that Clinic personnel have treated hundreds of child victims, and that this is typical of family medical

practices. Purl Decl. ¶ 9, App. 003. Dr. Purl previously served as medical director of an emergency department and as an emergency physician, where she routinely encountered children who were victims of sexual abuse. Purl Decl. ¶ 10, App. 003.

Each year, Dr. Purl and the Clinic cooperate with 10–12 requests for patient records from CPS to facilitate its investigations of suspected child abuse and neglect. Purl Decl. ¶ 13, App. 004. The demands from CPS are for the full, unredacted patient chart, whether or not the patient or his or her parent or guardian consent to the disclosure. Purl Decl. ¶ 13, App. 004. Dr. Purl and the Clinic comply with these demands, as is their duty under Texas law. Purl Decl. ¶ 13, App. 004.

In her role as a physician, Dr. Purl considers both a pregnant woman and her unborn child to be human persons, and her obligation as the treating physician is to care for both persons as her patients. Purl Decl. ¶ 6, App. 002. She believes that both mother and child are entitled to care according to sound medical judgment and conscience, and that both deserve the protection of the law. Purl Decl. ¶ 6, App. 002. She also believes that elective abortions, or medical treatments trying to achieve “gender transition” of children, harm patients’ health and the public health. Purl Decl. ¶ 6, App. 002–003.

Dr. Purl and the Clinic will incur compliance costs of at least \$6,785.00. Purl Decl. ¶¶ 15–16, 18, App. 005–006. HHS likely underestimated what the actual cost will be. Purl Decl. ¶ 15, App. 005. Dr. Purl estimates that conducting training for the Clinic employees alone could cost between \$1,800 and \$5,400. Purl Decl. ¶ 15, App. 005. In its calculations HHS did not appear to include loss of income from undertaking the compliance obligations. Yet during the time employees are receiving training, or Dr. Purl is conducting training and revising policies and notices, they cannot see patients and the Clinic cannot derive revenue from those services. Purl Decl. ¶¶ 17–18, App. 006–07. If the Clinic were closed for even one

hour to conduct staff training, it would lose at least \$1,385 in fees, copays, and insurance reimbursements. Purl Decl. ¶ 18, App. 006. Dr. Purl personally would lose between \$360 and \$480 per hour spent on compliance-related activities. Purl Decl. ¶ 18, App. 007.

II. HIPAA and the 2000 Privacy Rule

HIPAA was enacted in 1996 to “improve portability and continuity” and “simplify the administration of health insurance.” Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996). It includes privacy protections for patients’ personal information. As important here, HIPAA provides that a person who “knowingly ... discloses individually identifiable health information to another person, shall be punished” according to the criteria set forth in regulations HHS is to issue under the statute. 42 U.S.C. § 1320d-6.

HIPAA says nothing about particular medical procedures, abortion, “reproductive health care,” or gender transitions. Rather, it aims to protect the privacy of patient records, generally. There are no carve-outs for politically favored or disfavored procedures. And Congress did not write HHS a blank check to issue privacy regulations. HIPAA explicitly preserved the authority of states to collect information about abuse and public health, and therefore the ability of medical practitioners to cooperate with those investigations. “Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” *Id.* § 1320d-7(b).

In 2000, HHS adopted the “Privacy Rule,” entitled Standards for Privacy of Individually Identifiable Health Information. 65 Fed. Reg. 82,462. The Privacy Rule generally applies to regulated entities, including “health care provider[s] who

transmit[] ... health information in electronic form.” 45 C.F.R. § 160.102; *see id.* § 164.500. The Privacy Rule’s “major goal” “is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being.”¹

The Privacy Rule sets standards for using and disclosing protected health information (“PHI”) without the patient’s approval. These include disclosures: “for a law enforcement purpose to a law enforcement official,” 45 C.F.R. § 164.512(f); “[i]n response to an order of a court” or “a subpoena, discovery request, or other lawful process,” *id.* § 164.512(e)(1)(i), (ii); “to a health oversight agency for oversight activities authorized by law,” *id.* § 164.512(d)(1); and to a “public health authority ... for the purpose of preventing or controlling disease, injury, or disability,” including “the conduct of public health surveillance, public health investigations, and public health interventions,” *id.* § 164.512(b)(1)(i).

III. HHS conscripts HIPAA into its campaign against *Dobbs*.

In 2022, the U.S. Supreme Court ended a half-century of judicial usurpation of state authority, reversed *Roe* and *Casey*, and returned the power to regulate abortion “to the people and their elected representatives.” *Dobbs*, 597 U.S. 215, 259. The Court recognized the States’ “legitimate interests” in promoting “respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability.” *Id.* at 301 (internal citation omitted).

¹ See HHS Office for Civil Rights, *Summary of the HIPAA Privacy Rule* 1 (May 13, 2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.

HHS and Secretary Becerra scorned *Dobbs*, calling it “unconscionable.”² Secretary Becerra called abortion a “basic and essential part of health care,” and boasted of his decades-long “fight for reproductive freedom for everyone, no matter who you are, *where you live* or how much you make.”³ Secretary Becerra committed HHS “to ensure every American has ... the right to safe and legal abortion,” and said he had “directed every part of my Department to do any and everything we can,” and to “use every lever we have to protect access to abortion care.”⁴

Secretary Becerra’s opposition to *Dobbs* led to a coordinated, agency-wide campaign to contort HHS’s statutory authorities to promote abortion. He immediately took actions that other courts have since concluded exceeded HHS’s authority. He issued a mandatory memorandum from the Centers for Medicare & Medicaid Services (“CMS”) that tried to force emergency rooms and doctors to perform abortions under the 1986 law the Emergency Medical Treatment and Labor Act (“EMTALA”).⁵ Judge Hendrix permanently enjoined this mandate, the Fifth Circuit affirmed, and the Supreme Court denied HHS’s request for review.⁶

Through HHS’s Office for Civil Rights (“OCR”), which issued the 2024 Rule challenged here, Secretary Becerra issued a first-of-its-kind “guidance” ordering

² Press Release, U.S. Dep’t of Health & Hum. Servs., HHS Secretary Becerra’s Statement on Supreme Court Ruling in *Dobbs v. Jackson Women’s Health Organization* (June 24, 2022), <https://perma.cc/89AZ-RFL4>.

³ HHS Press Release, *supra* note 2 (emphasis added).

⁴ HHS Press Release, *supra* note 2.

⁵ See Mem. from CMS on Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (QSO-21-22-Hospitals- UPDATED JULY 2022) (July 11, 2022) (revised Aug. 25, 2022), <https://perma.cc/ND68-86SK>.

⁶ *Texas v. Becerra*, No. 5:22-CV-185-H, 2023 WL 2467216 (N.D. Tex. Jan. 13, 2023) (amended judgment permanently enjoining enforcement of the memorandum), *affirmed* 89 F.4th 529 (5th Cir. 2024), *cert. denied*, No. 23-1076, 2024 WL 4426546 (U.S. Oct. 7, 2024).

pharmacies to dispense drugs for abortion purposes, claiming authority from Section 504 of the Rehabilitation Act of 1973.⁷ Judge Counts rejected HHS’s motion to dismiss a challenge to that mandate, declaring that the guidance was transparently issued to require abortion drugs in response to *Dobbs*.⁸ OCR eventually revised the guidance to withdraw its abortion-drug mandate.⁹

At the same time, Secretary Becerra signaled he planned to use the 28-year-old HIPAA statute to promote abortion. In June 2022, OCR issued “guidance” tying HIPAA to “comprehensive reproductive health care services, including abortion care,” and citing the Secretary’s opposition to *Dobbs*.¹⁰ In January 2023, Secretary Becerra issued a report comprehensively documenting HHS’s broad efforts to promote abortion in opposition to *Dobbs*, and listing OCR’s HIPAA guidance as if it prohibits disclosures of information about abortion to pro-life states.¹¹ But because

⁷ See HHS OCR, Guidance to Nation’s Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services (July 13, 2022), <https://web.archive.org/web/20220713185710/https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf>.

⁸ *Texas v. HHS*, 681 F. Supp. 3d 665, 679 (W.D. Tex. 2023) (“Claiming now that the executive branch’s actions are not about abortion is disingenuous at best.”).

⁹ See HHS OCR, Guidance to Nation’s Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies (Sept. 29, 2023) (“Revised guidance: On September 29, 2023, OCR revised this guidance to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion.”), <https://perma.cc/S8ZB-WXRD>.

¹⁰ HHS OCR, HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care (June 20, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html>.

¹¹ HHS, Marking the 50th Anniversary of *Roe*: Biden-Harris Administration Efforts to Protect Reproductive Health Care (Jan. 19, 2023), <https://perma.cc/HUC4-4WBL>.

the 2000 Privacy Rule allowed doctors to disclose information for state investigations—consistent with HIPAA’s statutory admonition protecting state abuse and public health reporting laws—Secretary Becerra proposed this rule (the 2024 Rule).

IV. The 2024 Rule creates a “reproductive health care” carve-out to promote abortion and gender transition.

The 2024 Rule admits it reacts to the “[t]he Supreme Court’s decision in *Dobbs* [that] overturned *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, thereby enabling states to significantly restrict access to abortion.” 89 Fed. Reg. at 32,987. On announcing the 2024 Rule, Secretary Becerra stated, “We’re making it clear: you have the right to privacy—*Dobbs* did not take it away.”¹² To be sure, HIPAA was unaffected by *Dobbs*, and its 20-year-old privacy protections continue to shield patient information from improper disclosure. But the 2024 Rule distorted those privacy protections when it comes to HHS’s favored medical procedures—particularly abortion and gender transition interventions.

The 2024 Rule accomplishes this through expansive new restrictions on information relating to “reproductive health care,” broadly defined to include any “health care ... that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.” 45 C.F.R. § 160.103. The 2024 Rule’s preamble specifies that “reproductive health care” should be “interpreted broadly and inclusive of all types of health care related to an individual’s reproductive system” and that it “encompasses the full range of health care related to an individual’s reproductive health.” 89 Fed. Reg. at 33,005. That definition includes medical interventions associated with “gender identity.” 89 Fed. Reg. at

¹² Secretary Xavier Becerra (@SecBecerra), X (Apr. 22, 2024, 11:32 PM), <https://x.com/SecBecerra/status/1782432173665960400>, App. 008.

32,989 n.163; *see also* HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 88 Fed. Reg. 23,506, 23,521 n.180 (proposed Apr. 17, 2023).

From there, the 2024 Rule restricts covered entities from disclosing information to state officials and law enforcement in cooperation with efforts to obtain evidence of a crime, another potential violation of state law, or threats to public health related to “reproductive health care.” A covered entity may not disclose PHI sought:

- (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
- (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
- (3) [t]o identify any person [for these purposes].

45 C.F.R. § 164.502(a)(5)(iii)(A).

The 2024 Rule prohibits disclosure of PHI—even in response to lawful process—if:

- (1) [t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided[;]
- (2) [t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided[; or]
- (3) [t]he presumption [that the “reproductive health care” at issue was lawful] applies.

Id. § 164.502(a)(5)(iii)(B).

The 2024 rule creates a presumption that “reproductive health care” provided by another person was lawful. *See id.* § 164.502(a)(5)(iii)(B)(3) & (C). The

presumption is overcome only if (1) the covered entity has actual knowledge that the reproductive health care was not lawful or (2) the person requesting disclosure of PHI supplies “[f]actual information ... that demonstrates a substantial factual basis that the reproductive health care was not lawful.” *Id.* § 164.502(a)(5)(iii)(C).

Many requests for information must include an “attestation” meeting strict requirements set by HHS, untethered from state-law procedures. 45 C.F.R. § 164.509(a)(1); *see id.* § 164.512. If the attestation is deficient, disclosure is prohibited by the 2024 Rule even if it would be required by state law—and the HIPAA-covered entity bears the risk HHS will later determine the attestation was deficient. *See id.* § 164.509(a)(2).

The 2024 Rule also narrows a provision that previously allowed disclosures of information in response to an administrative request. It limits disclosures to times when a response is “required by law.” 45 C.F.R. § 164.512(f)(1)(ii)(C). Previously, information could be provided in response to an “administrative request” even if not required. *See id.* § 164.512(f)(1)(ii)(C) (2016). In other words, if compliance is voluntary, not mandatory, the 2024 Rule now prohibits disclosure.

The 2024 Rule also makes definitional changes intended to make it more difficult for pro-life states to investigate violations of their laws. It defines “person” to exclude any unborn child. 89 Fed. Reg. at 33,062. And it adds a definition of “public health” that excludes abortion and gender-transition interventions from “public health surveillance,” “public health investigation,” and “public health intervention.” *Id.* at 33,062–63 (codifying changes to 45 C.F.R. § 160.103).

The 2024 Rule’s special “reproductive health care” restrictions are one-sided. The 2024 Rule does not “prevent regulated entities from using or disclosing PHI to defend themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care.” *Id.* at 33,011. In other words, the 2024 Rule allows disclosure to *defend against* a claim or prosecution involving

“reproductive health care,” such as when a medical provider violates state laws against abortion or child “gender transitions,” but prevents doctors from disclosing similar information to further enforcement of such laws or protect public health.

ARGUMENT

A party seeking a preliminary injunction must show “(1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm without an injunction, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest.” *United States v. Abbott*, 110 F.4th 700, 706 (5th Cir. 2024) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

I. Dr. Purl and the Clinic have standing to challenge the 2024 Rule.

“When a plaintiff is an object of a regulation there is ordinarily little question that the [agency’s] action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.” *Texas Med. Ass’n v. HHS*, 110 F.4th 762, 773 (5th Cir. 2024) (cleaned up). Dr. Purl and the Clinic have standing to bring this challenge. Both Dr. Purl and the Clinic are subject to HIPAA. As “health care provider[s] who transmit[] health information in electronic form in connection with a transaction covered by” rules issued by HHS under HIPAA’s rulemaking authority, Dr. Purl, the Clinic, and Clinic employees are “covered entities” under 45 C.F.R. § 160.103.

The 2024 Rule requires Dr. Purl and the Clinic to generally comply with its disclosure restrictions by December 23, 2024, and issue updated notices of patient privacy by February 16, 2026. *See* 89 Fed. Reg. at 32,976. That means they will incur financial compliance costs. *See id.* at 33,049, 33,056. Such costs are “obvious” concrete harms, *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021), and are particularized to plaintiffs whom they affect directly, *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339–40 (2016). Plaintiffs should not need to “expos[e] themselves to

punishment or enforcement action” before receiving a ruling from this Court.

Braidwood Mgmt., Inc. v. EEOC, 70 F.4th 914, 927–28 (5th Cir. 2023).

II. Dr. Purl and the Clinic are likely to succeed on their APA claims.

Under the Administrative Procedure Act (“APA”), a reviewing court must “hold unlawful and set aside agency action” that is contrary to law. 5 U.S.C. § 706(2). In the 2024 Rule, HHS exceeded its statutory authority in two ways: *First*, it contradicted Congress’ express reservation of states’ authority to obtain abuse reporting and public health information, and it gerrymandered HIPAA around abortion and gender identity with no textual grounds for doing so. *Second*, HHS acted arbitrarily in making doctors guess which abortions are legal based on unsound assumptions.

A. The 2024 Rule conflicts with HIPAA’s preservation of state investigative authority.

The 2024 Rule illegally restrains disclosures made for abuse reporting and public health investigations that the HIPAA statute expressly preserves for state authorities. Like all Texans, Dr. Purl and her employees must report child abuse and neglect. Tex. Fam. Code § 261.101(a). But as a “professional” “licensed or certified by the state or who is an employee of a facility licensed, certified, or operated by the state and who, in the normal course of official duties or duties for which a license or certification is required, has direct contact with children,” Dr. Purl and each of her employees bears greater responsibility. *Id.* § 261.101(b). Texas requires such professionals having “reasonable cause to believe that a child has been abused or neglected or may be abused or neglected, or that a child is a victim of an offense under Section 21.11” of the Texas Penal Code (“Indecency With a Child”) to report the same within 48 hours. *Id.* The term “professional” “includes ... nurses, doctors, [and] employees of a clinic or health care facility that provides

reproductive services” *Id.* Under Texas law, the failure of a “professional” to report abuse or neglect is a Class A misdemeanor, or, as for some particularly vulnerable children, a felony. Tex. Fam. Code § 261.109. There is a similar reporting obligation for evidence of abuse of a vulnerable adult, such as someone with a disability. Tex. Hum. Res. Code § 48.051.

1. The 2024 Rule unlawfully limits disclosures about abuse and public health to state authorities.

The 2024 Rule defies Congress’s express directive that HHS may not limit disclosures necessary to protect children from abuse. Congress could not have been more clear: HHS cannot “limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, *child abuse*, birth, or death, public health surveillance, or *public health investigation* or intervention.” 42 U.S.C. § 1320d-7(b) (emphasis added). By definition, all of the “reproductive health care” restrictions in the 2024 Rule “limit” the ability of doctors to comply with mandatory abuse reporting laws and requests for information about public health. And, worse still, the 2024 Rule is not evenhanded—it expressly *allows* the very same disclosures to “defend against” alleged unlawful provision of “reproductive health care,” e.g., an illegal elective abortion. To be sure, the 2024 Rule creates a labyrinth of criteria where disclosure might be allowed despite the 2024 Rule’s additional restrictions. Those intricacies do not help, though, because the 2024 Rule creates limits on abuse and public health reporting while the statute allows *no* such “limit[s].” 42 U.S.C. § 1320d-7(b).

Courts have long recognized that HIPAA’s protection of PHI is limited by this and similar anti-preemption provisions. *Wassef v. Tibben*, 68 F.4th 1083, 1089 (8th Cir. 2023); *see also Seaton v. Mayberg*, 610 F.3d 530, 541 (9th Cir. 2010) (noting that Congress “evidently recogniz[ed] the well-established need for disclosure” in situations excepted from HIPAA’s preemption provision); *Citizens for Health v. Leavitt*,

428 F.3d 167, 172 (3d Cir. 2005). HIPAA's exceptions include the state-law reporting requirements and procedures relating to public health and child abuse explicitly referenced in 42 U.S.C. § 1320d-7(b).

2. The 2024 Rule unlawfully redefines “person” and “public health” to exclude state laws on abortion and gender transition.

HIPAA similarly does not authorize HHS to issue its own definition of “persons,” much less to do so to exclude unborn children. HIPAA does not define “person” or authorize HHS to define person. The Dictionary Act (Chapter 1 of Title 1 of the United States Code) is the default rule governing the definition of words in statutes. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 707 (2014). The Dictionary Act states that the word “person” includes “individuals.” 1 U.S.C. § 1. In 2002, Congress further amended the act with the Born-Alive Infants Protection Act, *id.* § 8, which states that “the words ‘person’, ‘human being’, ‘child’, and ‘individual’, shall include every infant member of the species homo sapiens who is born alive at any stage of development.”

The 2024 Rule enacts a definition of “person” not authorized by the Dictionary Act or HIPAA. It declares that under the Privacy Rule “person” means a “natural person (meaning a human being who is born alive).” 89 Fed. Reg. at 33,062. This deliberately excludes the unborn child. The change prevents Dr. Purl and the Clinic from considering the child a person. It prevents them from protecting the child’s information and from making necessary disclosures about abuse and public health.

There is no statutory authority for this change. Unlike the Dictionary Act, which says “person” *includes* “individuals” and *includes* infants “born alive,” the 2024 Rule enacts an *exclusive* definition so “person” does *not* include a human being before he or she is born alive. Nothing in the Dictionary Act or the Born-Alive

Infants Protection Act authorizes a definition of person that excludes the unborn. They are inclusive definitions, not exclusive definitions. The 2024 Rule lacks authority to change HIPAA to exclude the unborn.

The 2024 Rule similarly lacks authority to define “public health” to limit states’ exercise of their authority over medical practice when it comes to “reproductive health care.” *See* 89 Fed. Reg. 33,062–63 (codifying changes to 45 C.F.R. § 160.103). Nothing in HIPAA authorizes HHS to declare that the harms from abortion, medical gender-transition interventions, or other politically favored procedures do not count as “public health” concerns. On the contrary, as explained above, HIPAA explicitly states that the statute cannot be used to preempt state laws about obtaining information for public health. 42 U.S.C. § 1320d-7(b). Yet HHS claims authority to negate HIPAA’s anti-preemption clause by treating public-health concerns not shared by the political party controlling HHS as, by definition, not “public health.” Congress gave no such authority in HIPAA.

3. The 2024 Rule disrespects federalism.

The 2024 Rule’s constraints on covered entities contradict HIPAA’s preservation of state authority and respect for federalism. “Congress should make its intention clear and manifest if it intends to pre-empt the historic powers of the States.” *Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 65 (1989) (cleaned up). “This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere.” *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991). These structural principles protect “individual[s],” not just states. *Bond v. United States*, 564 U.S. 211, 222 (2011); *see also New York v. United States*, 505 U.S. 144, 181 (1992).

To say the least, HIPAA does not provide clear notice of the disclosure restrictions created by the 2024 Rule. *See Bennett v. New Jersey*, 470 U.S. 632, 638 (1985). Indeed, HIPAA expressly reserves state power to obtain such information from medical practitioners. Thus the 2024 Rule exceeds HHS’s constitutional power and privilege under the APA. These “grave constitutional concerns” are another reason the 2024 Rule is likely contrary to law. *Mexican Gulf Fishing Co. v. U.S. Dep’t of Com.*, 60 F.4th 956, 966–67 (5th Cir. 2023).

B. The 2024 Rule exceeds statutory authority by imposing special rules for abortion and “reproductive health care.”

HIPAA has nothing to say about abortion, gender transitions, or other “reproductive health care.” It does not mention particular medical conditions or procedures at all. It is about patient health information generally, and its terms are uniform across medical conditions and procedures. Nothing authorizes HHS to create special disclosure rules for procedures it favors and a different disclosure regime for every other kind of medical records.

The 2024 Rule makes no serious attempt to locate statutory authority for deploying HIPAA in the government-wide campaign against *Dobbs*. As sources of rulemaking authority, it generically cites HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Pub. L. No. 111-5, 89 Fed. Reg. at 32,980–84. HHS and Secretary Becerra try to explain the origins of their novel exceptionalism for “reproductive health care” by citing “recommend[ations]” by various medical bodies and the agency’s own vacillation on whether to issue this rule. 89 Fed. Reg. at 32,983. This is barely a rationale. And it is telling—even HHS does not claim there is statutory authority for the 2024 Rule’s abortion exceptionalism.

The Supreme Court has made it clear that agencies may not create nationwide policy shifts using statutes that have nothing to do with that issue. For

example, it was “not plausible that Congress gave EPA the authority to adopt” a regulation that would “force a nationwide transition away from the use of coal” based on statutory language lacking any such indication. *West Virginia v. EPA*, 597 U.S. 697, 735 (2022). And the Supreme Court blocked the Biden administration’s COVID vaccine regulation, citing both the purported statutory authority’s focus on workplace safety, “not broad public health measures,” as well as the “lack of historical precedent” for the rule. *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 117, 119 (2022). Similarly, HIPAA is focused (as relevant here) on patient information and privacy. It includes no reference to politically favored procedures, or to specific medical procedures at all.

As to precedent, there is none. HHS cites only one allegedly similar rule: Its previous amendments creating special rules for how to handle psychotherapy notes. 89 Fed. Reg. at 32,977–78. This is no precedent for using HIPAA to promote abortion, because psychotherapy *notes* are a type of health record, and HIPAA is a statute about health records. Abortion, gender transition, and “reproductive health care,” however, are not types of health records, they are procedures. HIPAA does not authorize different disclosure rules for different kinds of medical care.

Congress gave HHS no authority to use HIPAA as a weapon in policy disputes about abortion, gender-transition, or other “reproductive health care.” Because the agency lacks statutory authority, the 2024 Rule exceeds HHS’s authority and is contrary to law.

C. The 2024 Rule forces doctors to interpret the legality of abortion, making it arbitrary and capricious.

The APA’s arbitrary and capricious standard requires that agency action be “reasonable and reasonably explained.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). The standard applies to “all agency action, even ‘predictive

judgment[s] based on the evidence’ available.” *El Paso Elec. Co. v. FERC*, 76 F.4th 352, 364 (5th Cir. 2023) (quoting *Prometheus Radio*, 592 U.S. at 427).

The 2024 Rule is not “reasonably explained” because it requires physicians like Dr. Purl to make legal judgments. The 2024 Rule requires healthcare providers to determine which abortions are legal and which governmental requests for information are valid under federal law.

Under the 2024 Rule, HIPAA-covered entities must first determine whether an instance of “reproductive health care” was legal to determine whether they may disclose information relating to that procedure. 89 Fed. Reg. at 33,063 (codified at 45 C.F.R. § 164.502(a)(5)(iii)). In making that legal judgment, the 2024 Rule requires that a physician like Dr. Purl presume that “reproductive health care” is lawful unless she has actual knowledge of unlawfulness or the requesting law enforcement agency supplies “factual information ... that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.” 45 C.F.R. § 164.502(a)(5)(iii)(C). In many instances, medical practitioners must assess the accompanying “attestation” and determine whether it meets HHS’s strict requirements for validity. *Id.* § 164.509. These sorts of legal determinations are not within the scope of a healthcare provider’s usual competence. And yet, if the provider ends up being wrong she could be subject to significant civil and criminal penalties.

At the same time, the 2024 Rule’s presumption requires Dr. Purl and the Clinic to *ignore* what they do know about the law. In Texas, as in many other states, elective abortion is not legal. *See* Tex. Health & Safety Code § 170A.002. Neither are gender-transition procedures on children. *Id.* § 161.702. And it is unlawful to mail abortion-inducing drugs from outside the state. *See* 18 U.S.C. §§ 1461–62; Tex. Health & Safety Code § 171.063(b-1). It makes no sense for HIPAA-covered entities

in Texas (and many other states) to assume an abortion or gender-transitioning intervention was legal under these circumstances.

To further complicate matters, HHS considers a procedure legal any time “[t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.” 45 C.F.R. § 164.502(a)(5)(iii)(B)(2). Secretary Becerra has declared his office disagrees with *Dobbs*.¹³ And even today—two years after *Dobbs*—OCR maintains guidance claiming that abortions are lawful “under federal law” if they would have been treated as constitutionally protected under the *Roe/Casey* regime.¹⁴ And HHS has claimed that other federal statutes, like EMTALA, require abortions.¹⁵ So to comply with the 2024 Rule, covered entities must engage in legal analysis to determine whether “reproductive health care” is “authorized by federal law” and assess the facts underlying state requests for information.

The resulting scheme is contrary to law. The 2024 Rule does not explain or justify requiring such legal prognostication by HIPAA-covered entities. It gives no explanation or rationale for how a practitioner is supposed to determine whether the factual information provided with a request for information shows an abortion or gender transition was not legal. And it makes no attempt to justify considering

¹³ See HHS Press Release, *supra* note 2.

¹⁴ HHS OCR, Guidance on Nondiscrimination Protections under the Church Amendments (reviewed by OCR Feb. 3, 2023) (stating that “it is unconstitutional for a state to prohibit a patient from ending a pregnancy prior to fetal viability,” “a state statute that has the effect of placing a substantial obstacle in the path of a woman’s choice [to have a lawful abortion] cannot be considered a permissible means of serving its legitimate ends,” and federally funded or provided abortions are also lawful), <https://hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html>, App. 009–013.

¹⁵ See HHS OCR Guidance on Nondiscrimination Protections, *supra* note 14, App. 009–013, and CMS Mem., *supra* note 5.

certain abortions to be “authorized by Federal law” because HHS prefers *Roe* to *Dobbs*, even though *Dobbs* is controlling precedent. Must doctors apply the “undue burden” test of *Casey*, simply because HHS disagrees with *Dobbs*? And does the standard change when people with different views on *Dobbs* lead HHS or its civil rights office? It is not reasonable to require doctors to evaluate state law based on a constitutionally infirm standard, much less do so at their own peril when reporting information required or requested by states.

The 2024 Rule contains other actions, findings, and conclusions that are not reasonably explained. These include the justification for restrictively defining “person” and “public health,” expansively defining “reproductive health care,” 45 C.F.R. § 160.103, and how covered entities are to comply with the 2024 Rule’s new attestation requirements, 45 C.F.R. § 164.509. For all these reasons, the 2024 Rule is likely arbitrary and capricious, and thus contrary to law.

III. The 2024 Rule will cause irreparable harm.

A. Dr. Purl and employees of the Clinic have encountered and will encounter patients who they reasonably believe are victims of abuse or neglect. As professionals subject to the laws of the State of Texas, they have an obligation to report their findings to appropriate law enforcement authorities within 48 hours. Failure to report as required by Texas law could subject them to civil and criminal liability, including possible incarceration. Liability aside, Dr. Purl and the Clinic *wish to* comply with all abuse reporting laws to protect their patients, and they wish to cooperate with information requests authorized by state law, whether compliance is required or permissive. They fear, however, that they or their employees will violate the 2024 Rule if they report information consistent with state law.

At the same time, the 2024 Rule threatens civil and criminal consequences to Dr. Purl and Clinic employees if they *do* disclose PHI to protect patients and in

cooperation with law enforcement. That threat creates an irreconcilable conflict that will inevitably harm Dr. Purl and the Clinic. Complying with state law in violation of the 2024 Rule would subject Dr. Purl and the Clinic to significant civil penalties and even criminal consequences including up to 10 years in prison and \$250,000 in fines. 42 U.S.C. § 1320d-6(b). But refusing to disclose information to state agencies who seek it through lawful process, such as an administrative subpoena or court order, would subject Plaintiffs to possible liability and contempt proceedings—not to mention risk endangering patients’ health and safety.

B. The 2024 Rule also imposes financial costs. These include, at a minimum, the costs identified in the 2024 Rule, such as costs to update notices of patient privacy, develop new or modified policies and procedures, and revise training programs for staff. *See* 89 Fed. Reg. at 33,049, 33,052 tbl.4. As the sole owner of the Clinic, Dr. Purl must ensure such compliance. The 2024 Rule estimates that covered entities will incur at least \$132.23 to revise notices of patient privacy and \$24.46 to post them online, \$393.70 to develop new or modified policies and procedures, and \$100.77 for workforce training. 89 Fed. Reg. at 33,056. Based on the value of Dr. Purl’s time, the Clinic’s staff’s time, and the cost of legal services, Dr. Purl and the Clinic will incur costs at least in the amount estimated by the 2024 Rule, and likely more. Purl Decl. ¶¶ 15–18, App. 005–006.

The “nonrecoverable costs of complying with a putatively invalid regulation typically constitute irreparable harm.” *Rest. L. Ctr. v. U.S. Dep’t of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023). That is the case here, where sovereign immunity bars recovery of damages from HHS. *See id.* Plaintiffs need preliminary injunctive relief against both the disclosure restrictions and compliance costs beginning on December 23, 2024, and against the notice-related requirements and compliance costs beginning on February 16, 2026.

IV. The remaining factors favor Dr. Purl and the Clinic.

The final preliminary injunction factors are the balance of equities and the public interest; these factors “merge when the Government is the opposing party.” *Clarke v. Commodity Futures Trading Comm’n*, 74 F.4th 627, 643 (5th Cir. 2023) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)). The balance of equities tilts heavily in favor of plaintiffs. Covered entities will risk violating their state-law abuse-reporting obligations if they comply with the 2024 Rule, but HIPAA enforcement action if they do not. Law enforcement will be hindered in investigating crime and abuse, and children and women will be put at risk. HHS has no interest in covering up abuse and crime or interfering with states’ authority over medical practice and public health. Balanced against a slight delay in implementing HHS’s pro-abortion policy goals, there is no contest. HIPAA and its existing regulations will continue to protect patient privacy relating to “reproductive health care” just as before—on the same terms as all other PHI.

Secretary Becerra’s stated concern,¹⁶ is that *Dobbs* has made it harder to obtain an abortion in the United States, and HHS wants to ensure individuals “are comfortable accessing high-quality health care” and have easier access to abortion and gender-transition interventions. 89 Fed. Reg. at 32,984 (cleaned up). To be sure, many states have acted to protect life by regulating elective abortion and limiting gender-transition procedures to adults. Secretary Becerra does not agree with those choices, but the federal government has no legitimate interest in interfering with state policy judgments. And even if it did, the 2024 Rule does not change these policies—it only makes it easier for abuse and crime to persist undetected.

Finally, the APA restrains the federal bureaucracy from acting ultra vires. The 2024 Rule is arbitrary and capricious, as explained above, and “[t]he public

¹⁶ See HHS OCR Guidance on Nondiscrimination Protections, *supra* note 14, App. 009–013, and CMS Mem., *supra* note 5.

interest is served when administrative agencies comply with their obligations under the APA.” *Clarke*, 74 F.4th at 643–44 (quoting *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009)).

CONCLUSION

Dobbs returned “the authority to regulate abortion ... to the people,” 597 U.S. at 292, to be exercised through “the democratic process,” *id.* at 269. Disappointed with the policies chosen by many Americans, through their legislatures, Secretary Becerra issued the 2024 Rule to undermine state abortion laws. The Court should stay the 2024 Rule’s effective date under 5 U.S.C. § 705 or issue a preliminary injunction to protect Plaintiffs and the public from this excessive and arbitrary exercise of federal power.

Respectfully submitted this 12th day of November, 2024.

/s/ Natalie D. Thompson

Natalie D. Thompson

TX Bar No. 24088529

DC Bar No. 90026665

Matthew S. Bowman

DC Bar No. 993261

ALLIANCE DEFENDING FREEDOM

440 First Street NW, Suite 600

Washington, DC 20001

Telephone: (202) 393-8690

Facsimile: (202) 347-3622

nthomspon@ADFlegal.org

mbowman@ADFlegal.org

Julie Marie Blake

VA Bar No. 97891

ALLIANCE DEFENDING FREEDOM

44180 Riverside Parkway

Lansdowne, Virginia 20176

Telephone: (571) 707-4655

Facsimile: (571) 707-4790

jblake@ADFlegal.org

Counsel for Plaintiffs

CERTIFICATE OF CONFERENCE

I hereby certify that Defendants oppose this Motion for Preliminary Injunction. On November 8 and 9, 2024, Counsel for Plaintiffs conferred by email with Counsel for Defendants including John T. Lewis, III, Eric Beckenhauer, and Julie Straus Harris of the U.S. Department of Justice. Agreement could not be reached because counsel for Defendants would not agree to injunctive relief protecting Plaintiffs from the regulation before the December 23 compliance date, nor for the pendency of this case.

/s/ Natalie D. Thompson
Natalie D. Thompson